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EXAMINER
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HARTLEY, MICHAEL G

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PAPER

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**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

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*Ex parte* RUSSELL MUMPER and MICHAEL JAY

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Appeal 2008-2332  
Application 10/072,320  
Technology Center 1600

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Decided: June 27, 2008

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Before, TONI R. SCHEINER, DEMETRA J. MILLS, and RICHARD M.  
LEBOVITZ, *Administrative Patent Judges*.

MILLS, *Administrative Patent Judge*.

**DECISION ON APPEAL**

This is an appeal under 35 U.S.C. § 134. The Examiner has rejected the claims for obviousness. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

The following claim is representative.

33. A wax-film composite comprised of a pH-sensitive mucoadhesive layer and a water-insoluble wax layer.

*Cited References*

Eckenhoff	US 4,959,218	Sep. 25, 1990
Biegajski	US 5,700,478	Dec. 23, 1997

*Grounds of Rejection*

1. Claims 33-47, 51, and 56-57 stand rejected under 35 U.S.C. § 103(a) as obvious over Eckenhoff over Biegajski.

DISCUSSION

*Background*

“The present invention relates to compositions and methods to treat the skin and mucosal surfaces with mucoadhesive . . . wax-film composites that are pH-sensitive.” (Spec. 1.) The wax-film composites comprise a water-insoluble wax layer (B), and a pH-sensitive mucoadhesive film-forming layer (A), as shown in Figure 1, reproduced below:

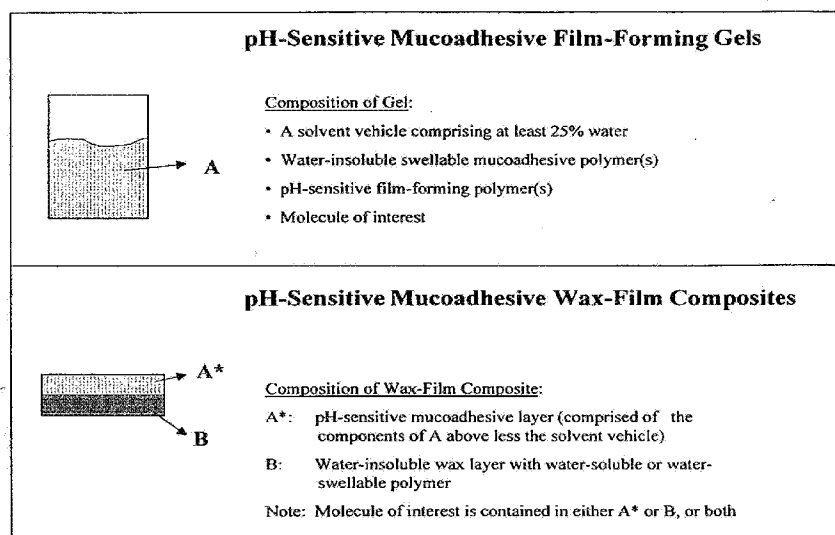


Figure 1 shows a wax-film composite comprising a water-insoluble wax layer (B), and a pH sensitive mucoadhesive layer (A) comprising a pH-

sensitive film forming polymer and a water-insoluble mucoadhesive polymer (without a solvent vehicle).

The Specification defines a “pH-sensitive mucoadhesive wax-film composite” as a bi-layer film comprised of a pH-sensitive mucoadhesive layer and a water-insoluble wax layer (Spec. 12). For bonding the two layers of the bi-layer wax film composite, it is preferred that the water-insoluble wax layer contain at least one water-soluble or water-swellaable agent. The water-soluble or swellaable polymer may be tragacanth, polyvinyl pyrrolidone, polyvinyl alcohol, cross-linked polyacrylic acid, polyethylene glycol, a cellulose polymer derivative or other suitable pharmaceutical polymer that is water-soluble or water-swellaable. (Spec. 7-8.)

The pH-sensitive mucoadhesive layer of the wax-film composite includes at least one water-insoluble swellaable mucoadhesive polymer and at least one pH-sensitive film forming polymer (Spec. 6.) The water insoluble swellaable mucoadhesive polymer is a polyacrylic acid cross-linked with polyalkenyl ether or divinyl glycol and, preferably, is Noveon or Carbomer. (Spec. 6-7.)

The Specification defines the term “pH-sensitive” as a “substance that is affected by changes in pH so that the substance changes conformation, charge, solubility, or combinations thereof” (Spec. 16). Examples of pH-sensitive film-forming polymers that meet these criteria are Eudragits and cellulose acetate phthalate polymers, or derivatives thereof (Spec. 16). Eudragits are synthetic cationic and anionic polymers of methacrylic acid and methacrylic acid esters in varying ratios (*id.*).

1. Claims 33-47, 51, and 56-57 stand rejected under 35 U.S.C. § 103(a) as obvious over Eckenhoff over Biegajski.

*Claim Interpretation*

Claim construction begins with the words of the claim. *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1341 (Fed. Cir. 2001). Generally, terms in a patent claim are given their plain, ordinary, and accustomed meaning to one of ordinary skill in the relevant art. *Id.* After identifying the plain meaning of a disputed claim term, the court examines the written description and the drawings to determine whether use of that term is consistent with the ordinary meaning of the term. *Day Int'l, Inc. v. Reeves Bros., Inc.*, 260 F.3d 1343, 1348 (Fed. Cir. 2001). This heavy presumption in favor of the ordinary meaning of claim language as understood by one of ordinary skill in the art is overcome: (1) where the patentee has chosen to be his or her own lexicographer by clearly setting forth an explicit definition for a claim term; or (2) where the term chosen by the patentee so deprives the claim of clarity that there is no means by which the scope of the claim may be ascertained from the language used. *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 990 (Fed. Cir. 1999).

Claim 33 recites a wax-film composite comprised of

- A. a pH-sensitive mucoadhesive layer, and
- B. a water-insoluble wax layer.

Upon review of the Specification and drawings we find the term “pH-sensitive mucoadhesive layer” as claimed is specifically defined as a combination of a pH-sensitive film-forming polymer and a water-insoluble mucoadhesive polymer. (Spec. 5-6, Fig 1.)

The Examiner finds that

Eckenhoff et al ... disclosed a drug delivery device made of wax layer (col 15, lin 1-15, and lin 49) comprising layers (col 16, lin 29-39) adapted to take several forms, shapes and sizes (col 16, lin 24) made of polymers (e.g. Carbopol; col 11, lin 54) for delivering medicaments to subcutaneous spaces in an animal or human, e.g. buccal, cervical, oral sites (col 7, lin 15-25).

(Ans. 4.)

The Examiner acknowledges that Eckenhoff does not specifically use the terms pH-sensitive or mucoadhesive (Ans. 5), but contends that Carbopol is an adhesive polymer that can attach to the skin (Ans. 6) and is pH-sensitive (Ans. 7). The Examiner relies on Biegajski for the disclosure of double layered, mucoadhesive drug delivery devices wherein the adhesive layer and the second polymer layer contain a drug to be delivered. (Ans. 5.)

The Examiner finds that

Biegajski [] disclosed the use of Eudragit polymethacrylate copolymers (col 22, lin 15) and Carbopol 934 (col 28, lin 40-45) for making the adhesive layer for the drug delivery device... Biegajski [] disclosed [a] wax-film composite wherein the mucoadhesive layer is a copolymer of methacrylic acid esters with diethylaminoethyl methacrylate (col 33, lin 55-60).

(Ans. 5.)

The Examiner concludes that:

One of ordinary skill would have been motivated to make [a] drug delivery device using polyacrylic acid cross-linked with

polyalkenyl ether or divinyl glycol as the material for making the wax-film composite, ... for the delivery device to deliver the active substance in a time more than 1 hr as claimed by applicant.

(Ans. 4-5.)

Appellants, on the other hand, contend that

[T]he cited art, taken alone or in combination, does not teach or suggest the bonded, bi-layer film including (1) a pH-sensitive mucoadhesive layer and (2) a water-insoluble wax layer of claim 33 and as defined by the specification. ... Eckenhoff is directed to a dispensing device that uses a driving member (*e.g.*, a swellable hydrophilic polymer) to push a beneficial agent (*e.g.*, a drug) through a wall, *via* an orifice, into an animal.

(Br. 8.) In addition, Appellants argue that Eckenhoff does not teach a pH-sensitive mucoadhesive. (Br. 5.) Appellants further argue that “the wax of Eckenhoff is not bonded to or associated with any mucoadhesive layer...(a mucoadhesive is totally absent in Eckenhoff...)” (Reply Br. 5.)

When determining whether a claim is obvious, an Examiner must make “a searching comparison of the claimed invention – *including all its limitations* – with the teaching of the prior art.” *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis added). Thus, “obviousness requires a suggestion of all limitations in a claim.” *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)). Moreover, as the Supreme Court recently stated, “*there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.*” *KSR Int'l v. Teleflex*

*Inc.*, 127 S. Ct. 1727, 1741 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (emphasis added)).

Upon review of the evidence of record, we do not find sufficient evidence to establish a prima facie case of obviousness of the claimed subject matter. In particular, we do not find that Eckenhoff discloses a wax-film composite comprised of A.) a pH-sensitive mucoadhesive layer, which is a combination of a pH-sensitive film-forming polymer and a water-insoluble mucoadhesive polymer and B.) a water-insoluble wax layer, as claimed. In Eckenhoff, the carbopol or carbomer driving member portion of the delivery device 17 (Fig. 2b) does not form a wax film composite with delivery device microcrystalline wax interface layer between the driving member and the drug. (Eckenhoff, col. 15, ll. 1-10.) We do not find that the Examiner has provided evidence that the carbopol is in contact with the wax film.

Nor do we find that Biegajski describes a composition as claimed, or makes up for the deficiencies of Eckenhoff. Biegajski discloses a three layer device having a mucoadhesive layer 44 containing a substance to be delivered which is overlain by a water-soluble pressure sensitive adhesive layer 46. (Biegajski, col. 17, ll. 45-64.) Thus, Biegajski does not describe a bilayer wax film composite, as claimed having a pH-sensitive mucoadhesive layer in combination of a pH-sensitive film-forming polymer and a water-insoluble mucoadhesive polymer. The combination of Eckenhoff and Biegajski fails to disclose the invention as claimed.

In view of the above, the obviousness rejection is reversed.



Appeal 2008-2332  
Application 10/072,320

SUMMARY

The obviousness rejection is reversed.

REVERSED

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